PATENT COOPERATION TREATY

| From the INTERNATIONAL SEARCHING AUTHORITY | | | | | | | | |
|--|---|---------------------|---|--------------------|--|---------|----------------------------------|--|
| To: | · · | | | RE | D'D 2 0 DEC 200 | 5 | PCT | |
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| see form PCT/ISA/220 | | | | | WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY | | | |
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| | | | | (PCT Rule 43bis.1) | | | | |
| | | | | | | | | |
| | | • | | | 1 | see foi | rm PCT/ISA/210 (second sheet) | |
| Applicant's or agent's file reference | | | | | TOD FURTHER ACTION | | | |
| | form PCT/ISA/2 | | FOR FURTHER ACTION See paragraph 2 below | | | | | |
| | national application | | International filing da | ate (| day/month/year) | - 1 | riority date (day/month/year) | |
| PC | T/NL2005/00013 | 3 | 23.02.2005 | | | 2 | 3.02.2004 | |
| Inter | national Patent Clas | sification (IPC) or | both national classifica | tion | and IPC | | | |
| A61 | F2/00 | | | | | | | |
| Appl | licant | | · · · · · · · · · · · · · · · · · · · | | | | · | |
| | NGENENGEL R | ESEARCH & D | EVELOPMENT B | .V. | | | | |
| | | | | | | | | |
| 1. | This opinion co | ontains indication | ons relating to the | fol | lowing items: | | • | |
| | , · | | | | J | | | |
| | ⊠ Box No. I | Basis of the op | oinion | | | | | |
| | ☐ Box No. II | Priority | nent of opinion with | rod | ard to novelty inver | tivo s | ten and industrial applicability | |
| | ☐ Box No. IV Lack of unity of invention ☑ Box No. V Reasoned statement under Rule 43 | | regard to novelty, inventive step and industrial applicability 3bis.1(a)(i) with regard to novelty, inventive step or industrial tions supporting such statement | | | | | |
| | | | | | | | | |
| | ☐ Box No. VI | Certain docum | | | o oupporting, ocon o | | | |
| | Box No. VII | | s in the international | apı | olication | | | |
| i | | | ations on the intern | | | | · | |
| 2. | FURTHER ACT | | | | • • | | | |
| - . | If a demand for international preliminary examination is made, this opinion will usually be considered to be a | | | | ever, this does not apply where | | | |
| | the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered. | | | | | | | |
| | If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. | | | | | | | |
| | For further optio | ns, see Form PC | CT/ISA/220. | | | | | |
| 3. | | | | | | | | |
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| | · | | | | | | | |

Name and mailing address of the ISA:

Authorized Officer

)

European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016

Germano, A

Telephone No. +31 70 340-4202



WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/NL2005/000133

| _ | Box No. I Basis of the opinion |
|----|---|
| 1. | With regard to the language , this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item. |
| | This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)). |
| 2. | With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of: |
| | a. type of material: |
| | ☐ a sequence listing |
| | ☐ table(s) related to the sequence listing |
| | b. format of material: |
| | ☐ in written format |
| | ☐ in computer readable form |
| | c. time of filing/furnishing: |
| | ☐ contained in the international application as filed. |
| | filed together with the international application in computer readable form. |
| | furnished subsequently to this Authority for the purposes of search. |
| 3. | In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished. |
| 1 | Additional comments: |

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

No:

.

3-6 1,2

Inventive step (IS)

Yes: Claims

No: Claims

Claims

1-6

Industrial applicability (IA)

Yes: Claims No: Claims 1-6

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

PCT/NL2005/000133

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The document US-A-6 231 617 describes the closest prior art to the present application, see figs. 3-5 and the relevant description.

In particular this document discloses (the references in parentheses applying to this document, the wording adheres to the wording of claim 1):
"a liner (10) for connecting a prosthesis with the stump of an amputated lower leg, comprising a stocking (11) from a substantially flexible material for surrounding the stump with a first, open end (14) for receiving the stump therethrough, and a second, closed end (12) which is, on the outside, provided with coupling means (13) for coupling to the prosthesis, wherein the stocking (11) is, on inside, provided with a substantially form retaining disc (18a) for supporting the end of the stump, and wherein the substantially form-retaining disc (18a) is substantially non-round in view from the open end (14) of the stocking.

This disclosure corresponds to the subject-matter of claim 1 which therefore is not new and does not meet the requirements of Art. 33(2) PCT.

- 2. The features of claims 2 are also disclosed, in combination with the features of claim 1, in said US-A-6 231 617. Therefore claim 2 is not new and does not meet the requirements of Art. 33(2) PCT.
- 3. The features of claims 3 to 6 are not described in said US-A-6 231 617. Therefore the subject-matter of claims 3 to 6 is new and meets the requirements of Art. 33(3) PCT.
- 3.1 However, these features merely refer to particular configurations and forms of the retaining disc. The skilled man would not to have to apply an inventive ingenuity in order to arrive to these forms, according to the circumstances.

 Moreover these forms are suggested in US-A-5 529 575.

Therefore claims 3 to 6 do not involve an inventive step and do not meet the requirements of Art. 33(3) PCT

Re Item VII

Certain defects in the international application

- 4. Independent claim should be cast in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document US-A-6 231 617) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
 - In the present case however it appears that a new claim 1 to be filed should contain in its preamble at least all of the features of present claim 1.
- 5. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 6. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document US-A-6 231 617 is not mentioned in the description, nor is this document identified therein.
- 7. The description should be put in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

PATENT COOPERATION TREATY

| To: | | | REC'D 20 DEC | | PCT | |
|--|---|--|--|--|--|--|
| see form PCT/ISA/220 | | | WPO PCT WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) | | | |
| | | | Date of mailing (day/month/yea | | m PCT/ISA/210 (second sheet) | |
| | icant's or agent's file reference form PCT/ISA/220 | | | FOR FURTHER ACTION See paragraph 2 below | | |
| | national application No. T/NL2005/000133 | International filing of 23.02.2005 | late (day/month/year) | e (day/month/year) Priority date (day/month/year) 23.02.2004 | | |
| International Patent Classification (IPC) or both national classification and IPC A61F2/00 | | | | | | |
| | icant NGENENGEL RESEARCH & | DEVELOPMENT I | 3.V. | | | |
| This opinion contains indications relating to the following items: | | | | | | |
| 1. | This opinion contains indicat | ions relating to the | e following items: | | | |
| 1. | Box No. I Box No. II Box No. III Box No. III Non-establish | pinion ment of opinion with | | nventive st | tep and industrial applicability | |
| 1. | Box No. I Box No. II Box No. III Box No. IV Box No. IV Box No. V Box No. V Reasoned str | pinion ment of opinion with of invention atement under Rule | n regard to novelty, ir 43 <i>bis</i> .1(a)(i) with reg | ard to nov | relty, inventive step or industrial | |
| 1. | Box No. I Box No. II Box No. III Box No. IV Box No. IV Box No. V Box No. V Reasoned str | pinion ment of opinion with of invention atement under Rule of citations and explan | n regard to novelty, in | ard to nov | relty, inventive step or industrial | |
| 1. | Box No. I Box No. II Priority Box No. III Non-establish Box No. IV Lack of unity Box No. V Reasoned strapplicability; Box No. VI Certain docur Box No. VII Certain defect | pinion ment of opinion with of invention atement under Rule o citations and explana ments cited ts in the internationa | n regard to novelty, ir 43 <i>bis</i> 1(a)(i) with reg ations supporting suc al application | ard to nov | relty, inventive step or industrial | |
| | Box No. I Box No. II Priority Box No. III Non-establish Box No. IV Lack of unity Box No. V Reasoned strapplicability; Box No. VI Certain docur Box No. VII Certain observance Certain observance | pinion ment of opinion with of invention atement under Rule o citations and explana ments cited ts in the internationa | n regard to novelty, ir 43 <i>bis</i> 1(a)(i) with reg ations supporting suc al application | ard to nov | relty, inventive step or industrial | |
| 2. | Box No. I Basis of the C Box No. II Priority Box No. III Non-establish Box No. IV Lack of unity Box No. V Reasoned strapplicability; Box No. VI Certain docur Box No. VII Certain defect Box No. VIII Certain obser | pinion ment of opinion with of invention atement under Rule citations and explana ments cited ts in the internationa vations on the international Preliminary Exar | n regard to novelty, in 43 <i>bis</i> .1(a)(i) with regations supporting such a application national application on is made, this opinining Authority ("IPE are to be the IPEA are | ard to nov th stateme on will usu EA"). Howe | relty, inventive step or industrial ent ually be considered to be a ever, this does not apply where sen IPEA has notifed the | |
| | Box No. I Basis of the company of the priority Box No. II Priority Box No. III Non-establish Box No. IV Lack of unity Box No. V Reasoned strapplicability; Box No. VI Certain documants Box No. VII Certain defector of the lack of the lack of unity Box No. VIII Certain defector of the lack of the lac | pinion ment of opinion with of invention atement under Rule citations and explana- ments cited ts in the internationa vations on the International Preliminary examination all Preliminary Examination of 66.1 bis(b) that write cove, considered to lead to the cover of the cover and the cover are t | a regard to novelty, in 43 <i>bis</i> .1(a)(i) with regard to novelty, in 43 <i>bis</i> .1(a)(i) with regard and application and application on is made, this opinimining Authority ("IPI one to be the IPEA are then opinions of this I appropriate, with ame | ard to noven statement on will usued the chonternation of the IPE/ | relty, inventive step or industrial ent relty, inventive step or industrial e | |
| | Box No. I Basis of the complete Box No. II Priority Box No. III Non-establish Box No. IV Lack of unity Box No. V Reasoned strapplicability; Box No. VI Certain docur Box No. VII Certain defect Box No. VIII Certain observation of the International priority applicant chooses an Author International Bureau under Rul will not be so considered. If this opinion is, as provided at submit to the IPEA a written remonths from the date of mailing | pinion Imment of opinion with of invention Itement under Rule citations and explana ments cited Its in the international vations on the International Preliminary Examinational Preliminary Examinational Preliminary Examinations of 66.1 bis(b) that write cove, considered to be of Form PCT/ISA/2 | a regard to novelty, in 43 <i>bis</i> .1(a)(i) with regard to novelty, in 43 <i>bis</i> .1(a)(i) with regard and application and application on is made, this opinimining Authority ("IPI one to be the IPEA are then opinions of this I appropriate, with ame | ard to noven statement on will usued the chonternation of the IPE/ | velty, inventive step or industrial ent ually be considered to be a ever, this does not apply where sen IPEA has notifed the al Searching Authority A, the applicant is invited to before the expiration of three | |
| | Box No. I Basis of the complete Box No. II Priority Box No. III Non-establish Box No. IV Lack of unity Box No. V Reasoned strapplicability; Box No. VI Certain docum Box No. VII Certain defect Box No. VIII Certain observable Box No. VIII Certain observable FURTHER ACTION If a demand for international prioritien opinion of the International prioritien applicant chooses an Authoritien applicant chooses an Authoritien applicant chooses and authoritien authorities are provided at submit to the IPEA a written remonths from the date of mailing whichever expires later. | pinion Iment of opinion with of invention Itement under Rule citations and explana- ments cited Its in the international vations on the International Preliminary examinational Preliminary Examination (Inc.) The provided HTML in the President Preliminary Examination (Inc.) The president Preliminary Examin | a regard to novelty, in 43 <i>bis</i> .1(a)(i) with regard to supporting such all application national application on is made, this opiniming Authority ("IPI one to be the IPEA arten opinions of this I be a written opinion of appropriate, with ame 20 or before the expirate. | ard to noven statement on will usued the chonternation of the IPE/ | velty, inventive step or industrial ent ually be considered to be a ever, this does not apply where sen IPEA has notifed the al Searching Authority A, the applicant is invited to before the expiration of three | |

Name and mailing address of the ISA:

Authorized Officer

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Germano, A

Telephone No. +31 70 340-4202



WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/NL2005/000133

| | Box No. I | Basis of the opinion |
|----|----------------------------|--|
| 1. | With regard the languag | to the language , this opinion has been established on the basis of the international application in ge in which it was filed, unless otherwise indicated under this item. |
| | langua | pinion has been established on the basis of a translation from the original language into the following ge , which is the language of a translation furnished for the purposes of international search Rules 12.3 and 23.1(b)). |
| 2. | With regard | d to any nucleotide and/or amino acid sequence disclosed in the international application and to the claimed invention, this opinion has been established on the basis of: |
| | a. type of n | naterial: |
| 1 | □ as | equence listing |
| | □ tab | le(s) related to the sequence listing |
| | b. format o | f material: |
| | in v | vritten format |
| | □ in c | computer readable form |
| | c. time of fi | ling/furnishing: |
| | □ cor | ntained in the international application as filed. |
| ٠ | ☐ file | d together with the international application in computer readable form. |
| | ☐ furi | nished subsequently to this Authority for the purposes of search. |
| 3. | has be copies | ition, in the case that more than one version or copy of a sequence listing and/or table relating thereto een filed or furnished, the required statements that the information in the subsequent or additional is is identical to that in the application as filed or does not go beyond the application as filed, as priate, were furnished. |
| 4 | Additional | comments: |

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/NL2005/000133

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

3-6

No:

Claims

1,2

Inventive step (IS)

Yes: Claims

No: Claims

1-6

Industrial applicability (IA)

Yes: Claims

1-6

No: Claims

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

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In particular this document discloses (the references in parentheses applying to this document, the wording adheres to the wording of claim 1):
"a liner (10) for connecting a prosthesis with the stump of an amputated lower leg, comprising a stocking (11) from a substantially flexible material for surrounding the stump with a first, open end (14) for receiving the stump therethrough, and a second, closed end (12) which is, on the outside, provided with coupling means (13) for coupling to the prosthesis, wherein the stocking (11) is, on inside, provided with a substantially form retaining disc (18a) for supporting the end of the stump, and wherein the substantially form-retaining disc (18a) is substantially non-round in view from the open end (14) of the stocking.

This disclosure corresponds to the subject-matter of claim 1 which therefore is not new and does not meet the requirements of Art. 33(2) PCT.

- 2. The features of claims 2 are also disclosed, in combination with the features of claim 1, in said US-A-6 231 617. Therefore claim 2 is not new and does not meet the requirements of Art. 33(2) PCT.
- 3. The features of claims 3 to 6 are not described in said US-A-6 231 617. Therefore the subject-matter of claims 3 to 6 is new and meets the requirements of Art. 33(3) PCT.
- 3.1 However, these features merely refer to particular configurations and forms of the retaining disc. The skilled man would not to have to apply an inventive ingenuity in order to arrive to these forms, according to the circumstances.
 Moreover these forms are suggested in US-A-5 529 575.

Therefore claims 3 to 6 do not involve an inventive step and do not meet the requirements of Art. 33(3) PCT

Re Item VII

Certain defects in the international application

- 4. Independent claim should be cast in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document US-A-6 231 617) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
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- 6. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document US-A-6 231 617 is not mentioned in the description, nor is this document identified therein.
- 7. The description should be put in conformity with the claims as required by Rule 5.1(a)(iii) PCT.